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OCT 1 2 2001

510(k) Summary
Bionx Implants Inc.
BioCuff C™

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Blue Bell, PA 19422

Contacts: Gerard S. Carlozzi
President and Chief Executive Officer
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5629

Date prepared: August 30, 2001

Name of the device:

A.	Trade or Proprietary Name:	BioCuff C™
B.	Common Name:	Bioabsorbable soft tissue fixation fastener
C.	Classification Name:	Bioabsorbable soft tissue fixation fastener
D.	Device Product Code:	MAI

Predicate Device:

Bionx Implants Inc. BioCuff™ (K001378)

Intended Use:

Properly used, in the presence of adequate immobilization, absorbable BioCuff C™ screw/washer maintains proximity between soft tissue and bone to facilitate the soft tissue reattachment. BioCuff C™ loses its strength over 20 to 50 weeks while the lesion of the tendon is healing. This indication is completely identical with the previously cleared BioCuff™ (K001378).

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Also, like the predicate devices, the BioCuff C™ is not intended for use in and is contraindicated for:

1. Surgical procedures other than those listed.
2. Conditions that may compromise fixation with BioCuff C™ (osteopenic, comminuted bone, etc.).
3. Conditions that may retard healing (poor blood supply, past or potential infection, etc.).
4. Active infection.
5. Conditions that may limit the patient's ability or willingness to restrict activities or follow directions during the healing period.
6. Foreign body sensitivity to materials.

Device Description:

BioCuff C™ is composed of poly-L/D-lactide copolymer. This raw material is completely identical with the previously cleared Bionx Implants Inc. BioCuff™ (K001378).

The device description of BioCuff C™ screw and washer combination is as follows:
- Composed of poly-L/D-lactide copolymer
- Lengths 18, 28 and 36mm.
- Diameter 6.0 mm
- Cannulation for 1.5mm K-wire

The only modifications that were made are:
- Cannulated design for easier installation of the product
- Increased outer diameter
- Minor design changes in head of the screw and washer accordingly
- Revision of instrument set according to needs of cannulation. This means cannulated screwdriver, cannulated drill, grasper, cannulated bone tap, sterilization tray and K-wire. Instrument set is substantially equivalent to previously cleared Bionx Implants Inc. BioCuff™ screw/washer (K001378) and Cannulated SmartScrew (K974876, K992947).
- Introduction of new reference numbers
- Introduction of new trade name, BioCuff C™

Substantial Equivalence:

The minor technological differences between BioCuff C™ and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2001

Mrs. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants Ltd.
Hermiankatu 6-8 L
Tampere
Finland

Re: K013057
Trade Name: BioCuff C™
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MAI, HWC
Dated: September 6, 2001
Received: September 6, 2001

Dear Mrs. Tuija Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K013057

Device Name: BioCuff C™

Indications for Use:

Properly used, in the presence of adequate immobilization, absorbable BioCuff C™ screw/washer maintains proximity between soft tissue and bone to facilitate the soft tissue reattachment. The BioCuff C™ loses its strength over 20 to 50 weeks while the lesion of the tendon is healing.

The BioCuff C™ is not intended for use in and is contraindicated for: 1) Insufficient quality or quantity of bone, 2) Foreign body sensitivity to the implant material. Where the material is suspected a test should be made prior to implantation to rule out sensitivity. 3) Patients with active sepsis or infection. 4) Conditions, which tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing and rehabilitation period.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013057